UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Minneapolis Firefighters' Relief Association, individually and on behalf of all others similarly situated, Union Asset Management Holding AG, Oklahoma Firefighters Pension Fund, Carpenters Annuity Trust Fund for Northern California, and Carpenters Pension Trust Fund for Northern California, et al.,

Plaintiffs,

v.

Medtronic, Inc., William A. Hawkins, III, and Gary Eliss,

Defendants.

Civil No. 08-6324 (PAM/AJB)

MEMORANDUM AND ORDER

This matter is before the Court on Defendants' Motion to Dismiss. For the reasons that follow, the Motion is granted in part and denied in part.

BACKGROUND

Plaintiffs in this putative class action are institutional investors who invested in the common stock of Defendant Medtronic, Inc., between November 20, 2006, and November 17, 2008. Plaintiffs claim that Medtronic made false and misleading public statements about one of its medical products, the Infuse bone graft system, and that when those statements were revealed to be false, the value of Medtronic stock plunged.

According to the Amended Complaint, "INFUSE Bone Graft is a surgically-implanted

medical device containing a genetically engineered protein designed to stimulate bone growth." (Am. Compl. ¶ 1 (Docket No. 68).) Medtronic received approval from the Food and Drug Administration ("FDA") for certain specific uses of Infuse: "treatment of degenerative discs in the lower lumbar region of the spine, fractures of the tibia, and certain facial/oral surgeries." (Id.)

Plaintiffs' claims arise from what they characterize as Medtronic's intentional promotion of off-label uses for Infuse. A physician's use of a device in a manner not specifically approved by the FDA is not illegal. It is illegal, however, for a manufacturer to promote a device's off-label use. Plaintiffs contend that Medtronic engaged in just such promotion, and that eventually more than 85% of Infuse sales involved off-label use. (Id. ¶ 3.) By the end of the class period, the Infuse product generated approximately $800 million annually, or 6% of Medtronic's total corporate revenue. (Id. ¶ 40.) In the summer of 2008, the FDA issued a warning about a particular off-label use of Infuse and, several months later, Medtronic disclosed that it was the target of an investigation by the Department of Justice ("DOJ") regarding off-label use of Infuse. Shortly thereafter, Medtronic's stock fell more than 45% from its class-period high. (Id. ¶ 9.)

The Amended Complaint alleges violations of §§ 10(b) and 20, and Rule 10b-5, of the Securities and Exchange Act of 1934. 15 U.S.C. §§ 78j(b) and 78t(a); 17 C.F.R. § 240.10b-5. Section 10(b) makes it unlawful "to use or employ, in connection with the purchase or sale of any security . . ., any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe . . . ." 15 U.S.C. § 78j(b).

Rule 10b-5 quantifies the conduct proscribed by section 10(b), making it illegal

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statement made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. Section 20 imposes liability on a person who controls an entity that engages in the practices proscribed by section 10(b) and rule 10b-5. To that end, Plaintiffs have named individual Defendants in addition to corporate Defendant Medtronic. Defendant Arthur D. Collins, Jr., was Chairman of Medtronic's Board of Directors from April 2002 until August 2008, and was CEO from May 2002 to August 2007. (Am. Compl. ¶ 21.) Defendant William A. Hawkins was Chairman of the Board and CEO from August 2008 through the class period, and was President and CEO from August 2007 until August 2008. (Id. ¶ 22.) Defendant Gary L. Ellis was Senior Vice President and Chief Financial Officer ("CFO") from May 2005 through the class period. (Id. ¶ 23.)

In 2006, before the class period, Medtronic settled a whistleblower lawsuit with the DOJ. In that lawsuit, whistleblowers alleged that Medtronic had engaged in illegal marketing and sales practices, including paying improper consulting fees to doctors to promote products from Medtronic's Spinal division, which includes Infuse. Medtronic did not admit to any liability, but paid $40 million and entered into a "Corporate Integrity Agreement" with the Department of Health and Human Services. (Id. ¶ 84.) Among many other provisions, this

Agreement required Medtronic to ensure that any arrangements between Medtronic and physicians for consulting services complied with federal law. The Agreement was signed in July 2006, but did not become effective until after the class period. (Id. ¶ 86.) One of Plaintiffs' allegations is that Medtronic continued its payments to physicians after signing the Agreement, and specifically paid consulting physicians to promote the off-label use of Infuse. (Id. ¶ 87.)

Plaintiffs also claim that Medtronic made statements that would lead investors to believe that the strong sales of Infuse were based on FDA-approved uses and not off-label uses. According to Plaintiffs, if investors had known that more than 85% of Infuse sales were due to off-label uses, the investors could have better gauged the risk that the FDA would shut down off-label uses and would have been better informed about the stability of Medtronic's stock price. Because of Medtronic's allegedly misleading statements, however, Plaintiffs contend that they were led to believe that Infuse sales were stable and would continue to grow, when Medtronic knew or should have known that such sales, dependent as they were on non-approved uses of Infuse, were highly unstable and likely to lead to regulatory backlash, drop in sales, and a consequent fall in Medtronic's stock price.

Plaintiffs allege that Medtronic both implicitly and explicitly encouraged its sales force to promote the off-label use of Infuse. Plaintiffs rely on the testimony of 15 confidential witnesses for this allegation. Defendants point out that nine of these witnesses were not employed at Medtronic during the class period. Plaintiffs contend that all of the testimony tends to show company practice and also establishes how off-label sales of Infuse

came to comprise more than 85% of total Infuse sales.

The confidential witnesses assert that Medtronic actively promoted off-label uses for Infuse by, among other things, hosting physician meetings at which a Medtronic-paid consulting physician would give a presentation on off-label uses (id. ¶ 93), instructing its sales force in the off-label use of Infuse (id. ¶ 94), giving physicians literature about off-label uses for Infuse (id. ¶ 96) or putting Medtronic-paid consulting physicians in contact with other physicians who used Infuse for off-label procedures (id. ¶ 102), and advising physicians regarding the appropriate dosage of Infuse for off-label uses (id. ¶ 105). Plaintiffs claim that Medtronic set high sales targets for Infuse and knew or should have known that such high targets could be reached only through illegal promotion of off-label uses of Infuse. (E.g., id. ¶ 107.) However, Medtronic did not disclose to investors that sales of Infuse were highly dependent on unregulated, off-label uses of Infuse, or that it was encouraging such uses.

DISCUSSION

Generally, a Rule 12(b)(6) motion requires the court to assume all factual allegations in the complaint as true, and grant plaintiffs all reasonable inferences that may be drawn from the complaint. Fed. R. Civ. P. 12(b)(6); In re Navarre Corp. Sec. Litig., 299 F.3d 735, 741 (8th Cir. 2002). The complaint must only include "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007). However, when Congress adopted the Private Securities Litigation Reform Act ("PSLRA"), it heightened the pleading standards for securities fraud class action claims pursuant to Rule

12(b)(6). Navarre, 299 F.3d at 741; see 15. U.S.C. §§ 78j, 78t(a); 17 C.F.R. § 240.10b-5. The PSLRA was designed to encompass at the very least 9(b) pleading standards. Kushner v. Beverly Enters., Inc., 317 F.3d 820, 826 (8th Cir. 2003).

In order to proceed on claims brought under 10(b) and Rule 10b-5, Plaintiffs are required to allege four elements: (1) misrepresentations or omissions of material fact or acts that operated as fraud or deceit in violation of the rule; (2) causation, often analyzed in terms of materiality and reliance; (3) scienter; and (4) economic harm caused by the fraudulent activity occurring in connection with the purchase and sale of a security. In re K-Tel Int'l Sec. Litig., 300 F.3d 881, 888 (8th Cir. 2002). The Complaint must specify each misleading statement or omission and specify why the statement or omission was misleading. 15 U.S.C. § 78u-4(b)(1); Kushner, 317 F.3d at 826. It must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15. U.S.C. § 78u-4(b)(2); Navarre, 299 F.3d at 741 ("[I]nferences of scienter survive a motion to dismiss only if they are both reasonable and 'strong' inferences"). The ultimate issue before the Court is not whether Plaintiffs will prevail at trial, but rather whether Plaintiffs are entitled to proceed with their claim. In re Digi Int'l Sec. Litig., 6 F. Supp. 2d 1089, 1095 (D. Minn. 1998) (Tunheim, J.).

In March 2009, another Judge in this District dismissed a similar class-action lawsuit against Medtronic. In re Medtronic Inc. Sec. Litig., 618 F. Supp. 2d 1016 (D. Minn. 2009) (Kyle, J.). The allegations in that case were that Medtronic knew about problems with a lead in one of its defibrillator products but failed to disclose those problems to investors. When

the problems came to light, Medtronic's stock price fell. (The class period in that case was from March to October 2007, which is included in the class period here.) The court concluded that the plaintiffs' allegations did not state a claim under section 10(b), rule 10b-5, or section 20. Plaintiffs have appealed the dismissal, but the Court of Appeals has yet to schedule argument in that appeal.

Medtronic argued that the plaintiffs had failed to plead the required material falsity and that the complaint did not give rise to a strong inference of scienter. The court agreed that the plaintiffs had not pled material falsity, because the problems with the defibrillator lead were not statistically significant at the time plaintiffs accused Medtronic of failing to disclose those problems. The court also found that the plaintiffs did not sufficiently allege a strong inference of scienter with respect to the individual Defendants.

Defendants here contend that the instant matter is indistinguishable from the In re Medtronic matter and, like that case, must be dismissed.

A. Section 10(b) and Rule 10b-5 Claims

Defendants claim that Plaintiffs have failed to comply with the PSLRA in several ways. First, they contend that Plaintiffs' allegations regarding the alleged misleading statements are insufficient. Second, they assert that Plaintiffs have not sufficiently alleged scienter. Finally, they contend that Plaintiffs' causation allegations are insufficient.

1. Misrepresentations/Omissions

The Complaint must specify each false statement or misleading omission and explain why the statement was misleading. 15 U.S.C. § 78u-4(b)(1). Moreover, any misleading statement or omission must be material, that is, there must be "a substantial likelihood that the disclosure of the [] fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976). A statement or omission is not material if it "present[s] or conceal[s] such insignificant data that, in the total mix of information, it simply would not matter to a reasonable investor." Parnes v. Gateway 2000, Inc., 122 F.3d 539, 547 (8th Cir. 1997).

Defendants first argue that the statements and omissions at issue are immaterial because off-label use of a medical device is not illegal. Plaintiffs' allegations are not, however, that Defendants misrepresented the off-label use of Infuse. Rather, Plaintiffs contend that Defendants misrepresented the extent to which Medtronic's own promotion caused the significant off-label use, something that certainly is illegal. Moreover, Plaintiffs' allegations involving off-label use, rather than the promotion of that use, are not that the use itself was illegal but rather that the information about the proportion of sales attributable to off-label use would have been material to a reasonable investor. At this stage of the proceedings, the Court cannot say that the information about off-label use was immaterial as a matter of law. Thus, Plaintiffs have sufficiently pled materiality.

In the In re Medtronic case, the plaintiffs alleged that Medtronic violated the securities

laws by failing to disclose the extent to which Medtronic's defibrillator lead did not function properly. In re Medtronic, 618 F. Supp. 2d at 1023. The plaintiffs contended that these adverse events were material. However, the plaintiffs failed to show that the adverse events had a statistically significant relationship to the number of procedures performed successfully. Thus, the court found that the information about adverse events was not material as a matter of law. Id. at 1026. Here, on the other hand, statistical significance plays no role. Although Plaintiffs attempt to show Medtronic's knowledge about off-label use through the number of adverse events associated with that off-label use, the adverse events themselves are not at issue. In other words, there is no allegation that Medtronic should have disclosed the adverse events to investors, and thus no issue as to whether the number of adverse off-label events was statistically significant.

Defendants also contend that Plaintiffs have failed to sufficiently allege that Medtronic engaged in purposeful off-label promotion. Defendants' argument, in the main, is that the Court should not credit the testimony of the confidential witnesses. This is not an appropriate argument to make in a motion to dismiss. Although the PSLRA requires a heightened pleading standard, it does not require Plaintiffs to prove their case at the pleading stage. Plaintiffs have come forward with evidence that, if believed, establishes that Medtronic purposefully promoted the off-label use of Infuse. Defendants' Motion cannot be granted on this basis.

Finally, Defendants contend that the statements with which Plaintiffs take issue are not actionable. In the Amended Complaint, Plaintiffs list a multitude of allegedly false,

misleading, and materially incomplete statements that they contend failed to disclose: (1) that Infuse sales were "primarily dependent on off-label use of the product;" (2) that Medtronic continued to pay physician consultants large sums of money to promote the off-label use of Infuse; and (3) that Medtronic's salespeople were "actively marketing" Infuse for off-label use, thereby "risking the very regulatory actions, investigations, lawsuits, and declining sales that eventually resulted." (Am. Compl. ¶ 174.) The statements on which Plaintiffs rely for their claims fall into six general categories: (1) statements regarding general compliance with the law (id. ¶¶ 176, 221, 256); (2) statements regarding the growth in Infuse sales and attributing that growth to on-label uses of Infuse (id. ¶¶ 178, 181-82, 192-93, 200, 211, 213, 219, 226, 232, 236, 243, 245, 250, 253); (3) statements regarding Infuse sales growth that do not attribute that growth to any particular reason (id. ¶¶ 189, 210, 217-28, 224-25, 230-31, 238-39, 241, 249); (4) statements regarding FDA approval of Infuse in general (id. ¶¶ 179-80, 191); (5) statements predicting that Infuse sales growth would continue because Medtronic was seeking further FDA-approved uses for the product (id. ¶¶ 176, 195, 197, 204-08, 240, 251-52); and (6) statements regarding the corporate integrity agreement and other similar statements that either stated or implied that Medtronic's competitors were not complying with the law but that Medtronic was complying (id. ¶¶ 183-84, 190, 194, 202, 203, 212, 214, 220, 227, 233, 244, 246). The Court will examine each category to determine whether the statements are actionable.

a. **General Compliance**

Defendants contend that the first category of statements is too "soft" to be actionable.

(Defs.' Supp. Mem. at 20-21.) Defendants argue that statements about general compliance with the law are not actionable under Eighth Circuit precedent. (See id. (citing, inter alia, Kushner v. Beverly Enters., Inc., 317 F.3d 820, 830-31 (8th Cir. 2003)).) In Kushner, the court found that the defendants' statements concerning compliance with Medicare regulations were not actionable because there was no evidence that the defendants knew the statements were untruthful at the time they made the statements. Kushner, 317 F.3d at 831. The Kushner decision does not, however, stand for the broad proposition that all statements concerning general compliance with the law are not actionable. Rather, such statements are actionable if there is other evidence from which a plausible inference can be drawn that the speaker knew that the statements were false.

The statements at issue in this category are statements such as "[c]ompliance with the law and with the highest ethical standards is critical to Medtronic's continued collaboration with its physician customers" (Am. Compl. ¶ 176), or that Medtronic was "fully compliant with the law and industry standards." (Id. ¶ 221.) Even when viewed in light of the remainder of the allegations in the Amended Complaint, Plaintiffs have failed to establish that such general statements are actionable. Although Plaintiffs allege that Defendants were not complying with all applicable laws at all times, the rather amorphous contours of the allegedly illegal conduct in this case is such that the Court cannot infer from those allegations that any statement regarding general compliance with the law was knowingly untruthful when made. The general compliance statements are not actionable.

b. **Attributing Infuse sales growth to on-label use**

The second category of statements are statements that attribute the growth in Infuse sales to FDA-approved, on-label uses. (E.g., Am. Compl. ¶ 211 (increase in sales is "based on continued strong acceptance of INFUSE Bone Graft").) Such statements clearly are not "soft" statements of opinion. Rather, these statements convey "hard" information: Infuse's strong sales showing was due to the fact that physicians were continuing to use the product, with the implication that such increased use was on-label use. For example, a November 2006 Medtronic press release specifically juxtaposed "expanded surgeon adoption" of Infuse and expanded FDA approval for the product. (Id. ¶ 178.) Plaintiffs contend that such statements were false or misleading because Medtronic knew that the growth in Infuse sales was due to off-label uses and not to any increase in on-label uses or in new FDA approvals.

Information about why a product experiences increased sales growth, and the potential for the product to continue to experience that growth, is almost by definition the sort of information on which investors rely when making investment decisions. It is not a "prediction" or a "matter[] of opinion" that is not actionable. In re Sofamor Danek Group, Inc., 123 F.3d 394, 401 (6th Cir. 1997). This category of statements is actionable and Defendants' Motion as to this category fails.

c. **General statement about Infuse sales growth**

On the other hand, the general statements that Infuse experienced sales growth, with no explanation as to why or whether that growth would continue, are not actionable. (See, e.g., Am. Compl. ¶ 189 (commenting that growth in Spinal division was "largely driven by the continued growth of the legacy family" including Infuse); id. ¶ 231 (noting "solid growth

in our core Spinal business outside the U.S.").) The fact is that Infuse did experience strong sales; this information is not untruthful. Nor do the statements imply that Infuse growth was attributable to any particular factor. Without such an implication, the statements are not actionable.

d. **Statements about FDA-approved uses**

Plaintiffs also take issue with general statements about the FDA Advisory Panel's recommendation that Infuse be approved for oral maxillofacial uses. (E.g., id. ¶ 180 (quoting Hawkins that the Advisory Panel "recommended approval of INFUSE Bone Graft for use in the oral maxillofacial market, which signals an important step in the expansion of indications for INFUSE").) Plaintiffs contend that such statements implied that all uses of Infuse were approved uses. The connection between true statements about a new approved use and the alleged implication that therefore all uses are approved uses is too attentuated. A reasonable investor would not infer from these statements that all uses of Infuse were on-label uses. Rather, an investor would reasonably believe only that the FDA might continue to approve new uses for Infuse, which is not demonstrably false. This category of statements is not actionable.

e. **Predicting increased sales growth**

Some statements regarding FDA approval, however, did explicitly state that Infuse's strong sales growth would continue because Medtronic was seeking further on-label uses for the product. (E.g., id. ¶ 197 (Defendant Collins stated that Medtronic's strategy was to seek new on-label uses to drive Infuse sales.).) According to Plaintiffs, such statements are

actionable because Medtronic knew that Infuse's past and future sales depended on off-label uses, not on-label uses. These statements are similar to those in the second category, in that the statements either state or imply something allegedly false about Infuse: that on-label uses were responsible for the product's sales growth. This is "hard" information and, if Plaintiffs' allegations are true, it was also false information. This category of statements is actionable.

f. **Corporate Integrity Agreement and comparisons to competitors**

The final category consists of statements regarding the Corporate Integrity Agreement Medtronic signed to settle the whistleblower lawsuits and statements contrasting Medtronic's sales practices with those of Medtronic's competitors. (E.g., Am. Compl. ¶ 212 (stating that the Agreement "further strengthens [Medtronic's] employee training and compliance systems surrounding sales and marketing practices" and "reflects Medtronic's assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity"); id. ¶ 203 (noting the "aggressive sales practices" of Medtronic's competitors); id. ¶ 202 (Hawkins stated that "other things [] could happen that may make it difficult for [Medtronic's competitors] going forward").)

Medtronic's statements that the Agreement was evidence that Medtronic was complying with the law are at first glance quite similar to those in the first category discussed above. However, the statements in this final category are more specific than the general compliance statements in the first category. In particular, the statements about the Agreement told investors that Medtronic had taken steps to ensure that whatever problems were discovered in the DOJ investigation were solved, and that those steps included training

Medtronic sales staff regarding appropriate sales and marketing tactics. Medtronic has a duty to disclose "a belief as to the legality of [its] own actions" if it has "actual knowledge of wrongdoing." Kushner, 317 F.3d at 831. Plaintiffs contend that Defendants knew that the statements were not true because they knew that, despite the Agreement, Medtronic's sales staff were still engaging in the conduct that gave rise to the Agreement, namely paying physicians to promote the off-label use of Infuse. This is a different allegation from the general legal compliance allegation discussed previously, because this allegation is capable of being proved specifically true or specifically false. Thus, it is "hard" information, not "soft" information, and because Plaintiffs have alleged that Defendants knew that the statements were untruthful, they are actionable. Id.

On the other hand, statements criticizing the sales practices of Medtronic's competitors are not the type of "hard" information that is verifiably true or false. Plaintiffs argue that these statements implied that the competitors would be subject to regulatory scrutiny for their sales tactics, when in fact Medtronic was engaging in the same sorts of sales tactics but concealed that from investors. As with the statements discussed in the fourth category, this logical leap is too attenuated. The actual statements might be demonstrably true or false—Medtronic's competitors may or may not have engaged in "aggressive" sales practices and may or may not have faced regulatory scrutiny as a result. It is not the actual content of the statements with which Plaintiffs take issue, however. Rather, Plaintiffs assert that the statements amounted to a sort of corporate finger-pointing that was intended to make Medtronic look good when in fact Medtronic was doing what it accused its competitors of

doing. Plaintiffs' interpretation of the statements is not the only reasonable interpretation. Taking these statements in context, the Court cannot say that they would mislead a reasonable investor. In re NVE Corp. Sec. Litig., 551 F. Supp. 2d 871, 881 (D. Minn. 2007) (Davis, J.). The statements about Medtronic's competitors are not actionable.

g. **Conclusion**

Plaintiffs have succeeded in establishing that several categories of statements are actionable: statements that attributed the growth in Infuse sales to on-label uses of Infuse, statements predicting increased Infuse sales from additional on-label uses, and statements about Medtronic's efforts to comply with the Corporate Integrity Agreement. The remainder of the statements in the Amended Complaint are not actionable.

2. Scienter

Plaintiffs must set forth facts that give a strong reason to believe that there was reckless or intentional wrongdoing. Navarre, 299 F.3d at 745. Scienter may be established by: (1) facts demonstrating a conscious intent to deceive, manipulate, or defraud; (2) allegations of severe recklessness; or (3) allegations of opportunity or motive. Cornelia I. Crowell GST Trust v. Possis Med., Inc., 519 F.3d 778, 782 (8th Cir. 2008) (citing K-Tel, 300 F.3d at 893-94). Allegations of motivation or opportunity alone are insufficient to establish scienter, but coupled with actual knowledge or recklessness, such allegations bolster a plaintiff's showing of scienter. K-Tel, 300 F.3d at 894.

Plaintiffs' scienter allegations are, in part, allegations that because the individual Defendants were in senior management positions, they knew or should have known about

the off-label promotion and use of Infuse. In the other recent case involving Medtronic, the court found that because the defibrillator lead at issue comprised only 2% of Medtronic's total revenue, information about the lead "was not so important to Medtronic's continued success to support the inference that the individual Defendants must have known all information regarding it." In re Medtronic Inc. Sec. Litig., 618 F. Supp. 2d at 1034. Here, the Infuse product comprised 6% of Medtronic's total sales. There is no bright-line test for what proportion of revenue a product must occupy before knowledge about that product can be imputed to a company's senior management. Two percent may not be enough, but six percent is enough to raise at least a plausible inference that senior management would have known about a product. (See, e.g., Am. Compl. ¶ 206 (Defendant Hawkins's statement that Infuse is a "very important product"for Medtronic).)

Even if Infuse were not responsible for a significant percentage of Medtronic's revenue, however, the Amended Complaint alleges facts which, if true, give rise to a strong inference of scienter on the part of the individual Defendants. Plaintiffs quote extensively from statements these Defendants made portraying the growth in Infuse sales as attributable to the on-label use of Infuse and Medtronic's efforts to expand FDA approval. (See, e.g., Am. Compl. ¶¶ 251-52 (quoting Defendant Hawkins).) According to Plaintiffs, these statements were misleading because Hawkins knew that the vast majority of Infuse sales were not attributable to on-label use or to expanded FDA approval, but rather were attributable to off-label use of Infuse. See Navarre, 299 F.3d at 746 (describing "'classic' fact pattern giving rise to a strong inference of scienter" as "defendants made statements

when they knew or had access to information suggesting these public statements to be materially inaccurate"). This is both a reasonable and a strong inference of scienter, which is all that is required on a Motion to Dismiss. See Kushner, 317 F.3d at 827 ("[I]nferences of scienter tested under the [PSLRA] will not survive a motion to dismiss if they are only reasonable inferences—the inferences must be 'both reasonable and strong.'") (quoting Helwig v. Vencor, Inc., 251 F.3d 540, 551 (6th Cir. 2001)).

Moreover, Plaintiffs allege that these individual Defendants knew, because of the whistleblower lawsuits and settlement of those lawsuits, about Medtronic's physician-consulting program and the role that program played in the promotion of off-label uses of Infuse. Indeed, in the Agreement, Medtronic agreed that its senior management would monitor Medtronic's activities in this regard. Although the monitoring requirement may not have been in place during the class period, the Agreement itself was signed before the class period and thus management knew what was expected of them. To the extent the alleged off-label promotion depended on activities forbidden by the Agreement, Plaintiffs have succeeded in establishing an inference of scienter.

Plaintiffs have sufficiently alleged a strong inference of scienter on the part of the individual Defendants.

3. Causation

Finally, Defendants contend that Plaintiff have not pled loss causation. According to Defendants, Plaintiffs must show that the alleged misstatements or omissions, and not some other event, caused the drop in price. (Defs.' Supp. Mem. at 39, quoting Schaaf v.

Residential Funding Corp., 517 F.3d 544, 550 (8th Cir. 2008).) While it may be true that Medtronic revealed other negative information on the day before the stock value plunged, it is also true that some of the information revealed concerned Infuse. Thus, at this early stage, Plaintiffs have sufficiently alleged what they are required to allege: the "'truth [about Infuse] became known' to the market and caused the share price to decline." (Id. at 39-40, quoting Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347 (2005).) At the pleading stage, Plaintiffs are not required to eliminate every other potential cause for the price drop. Rather, they must allege facts which are plausible and, if true, establish causation. They have done that here, and the Motion to Dismiss for failure to plead causation is denied.

B. Section 20

Defendants' only argument with respect to section 20 liability is that Plaintiffs have not established the liability of Medtronic so that the individual Defendants cannot be subject to control-person liability. Because Plaintiffs' section 10 and rule 10b-5 claims succeed as to certain statements, the section 20 claims likewise succeed as to those statements.

CONCLUSION

Having thoroughly reviewed the allegations in the Amended Complaint, the Court has determined that some of the statements on which Plaintiffs' claims rely are not actionable as a matter of law. However, some statements are actionable, and Plaintiffs have sufficiently alleged a strong inference of scienter and the causation necessary to support their claims with respect to these statements. Accordingly, **IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss (Docket No. 71) is **GRANTED in part and DENIED in part**.

Dated: Wednesday, February 3, 2010

s/ Paul A. Magnuson
Paul A. Magnuson
United States District Court Judge